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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,499	01/10/2007	Peter Andrews	7730-71694-01	8366

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EXAMINER	
WOLLENBERGER, LOUIS V	
ART UNIT	PAPER NUMBER
1635	
MAIL DATE	DELIVERY MODE
04/02/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/550,499	ANDREWS ET AL.	
	Examiner	Art Unit	
	Louis Wollenberger	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5,6,8-12 and 14-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☒ Claim(s) *1-3,5,6,8-12 and 14-26* is/are objected to.

8)☒ Claim(s) *1-3, 5, 6, 8-12, and 14-22, and 26* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Notice to comply*.

DETAILED ACTION

Preliminary Amendment

Applicants' preliminary amendment to the claims, filed 9/20/05, is acknowledged. With entry of the amendment, claims 1-3, 5, 6, 8-12, and 14-26 are pending and subject to restriction as follows.

Claim Objections

1-3, 5, 6, 8-12, and 14-26 are objected to for the recitation "the nucleic acid sequence shown in any of Figures 9-16." Where possible, claims are to be complete in themselves. Incorporation by reference to a specific figure or table "is permitted only in exceptional circumstances where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim. Incorporation by reference is a necessity doctrine, not for applicant's convenience." *Ex parte Fressola*, 27 USPQ2d 1608, 1609 (Bd. Pat. App. & Inter. 1993) (citations omitted).

In the instant case, the sequences should be identified individually by SEQ ID NO: identifier not by reference to figures.

Correction is required.

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Claims 23-25 are objected to because the claims are directly or indirectly drawn to the method of "Claim 22A." There is no claim 22A in the application. Further, the numbering of a claim as by number and letter is improper. If the claims were intended to be drawn to Claim 22,

the claims remain inscrutable because claim 22 is drawn to a pharmaceutical composition not a method.

Accordingly, claims 23-25 have not been included in any of the groups below because the subject matter being claimed in each of claims 23-25 cannot be readily determined.

Correction is required. Correction may necessitate further restriction, depending on the amendment to the claims.

Specification/Drawings/Sequence Compliance

The disclosure is objected to because of the following: This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application clearly fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below or on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. The specification as filed does not comply with the requirements above, in particular 1.821(d) at least, because it contains nucleotide sequences of over 10 nucleobases each that are not identified by accompanying sequence identifiers.

For example, the sequences set forth in Figures 9-24 and at pages 24 and 29 of the specification do not contain SEQ ID NO: identifiers as required. This is but a sampling of the many sequences set forth in the instant application without SEQ ID NO: identifiers. Applicants are advised to review the entire application—claims, drawings, and specification—for complete compliance with the Sequence Rules.

Thus, the Examiner notes herein that the above listing of pages and figures which set forth examples in the specification of nucleotide sequences that require SEQ ID NO: is by way of illustration. In order to be fully responsive to this Office Action, Applicant should review this application in its entirety to ensure compliance with the requirements of 37 CFR 1.821 through 1.825 and to make all appropriate corrections.

Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g).

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-3, 5, 6, 8-12, and 14-22, and 26, drawn to an inhibitory RNA molecule designed with reference to the sequence shown in Fig. 9, and to an expression cassette and vector thereof, and to a method for inhibiting division of a cancer cell comprising the use of said RNA molecule. Election of this group requires the further election of a single species of the claimed invention from claims 3, 15, 16, and 21, as explained below.

Group II, claim(s) 1-3, 5, 6, 8-12, and 14-22, and 26, drawn to an inhibitory RNA molecule designed with reference to the sequence shown in Fig. 10, and to an expression cassette and vector thereof, and to a method for inhibiting division of a cancer cell comprising the use of said RNA molecule. Election of this group requires the further election of a single species of the claimed invention from claims 3, 15, 16, and 21, as explained below.

Group III, claim(s) 1-3, 5, 6, 8-12, and 14-22, and 26, drawn to an inhibitory RNA molecule designed with reference to the sequence shown in Fig. 11, and to an expression cassette and vector thereof, and to a method for inhibiting division of a cancer cell comprising the use of said

RNA molecule. Election of this group requires the further election of a single species of the claimed invention from claims 3, 15, 16, and 21, as explained below.

Group IV, claim(s) 1-3, 5, 6, 8-12, and 14-22, and 26, drawn to an inhibitory RNA molecule designed with reference to the sequence shown in Fig. 12, and to an expression cassette and vector thereof, and to a method for inhibiting division of a cancer cell comprising the use of said RNA molecule. Election of this group requires the further election of a single species of the claimed invention from claims 3, 15, 16, and 21, as explained below.

Group V, claim(s) 1-3, 5, 6, 8-12, and 14-22, and 26, drawn to an inhibitory RNA molecule designed with reference to the sequence shown in Fig. 13, and to an expression cassette and vector thereof, and to a method for inhibiting division of a cancer cell comprising the use of said RNA molecule. Election of this group requires the further election of a single species of the claimed invention from claims 3, 15, 16, and 21, as explained below.

Group VI, claim(s) 1-3, 5, 6, 8-12, and 14-22, and 26, drawn to an inhibitory RNA molecule designed with reference to the sequence shown in Fig. 14, and to an expression cassette and vector thereof, and to a method for inhibiting division of a cancer cell comprising the use of said RNA molecule. Election of this group requires the further election of a single species of the claimed invention from claims 3, 15, 16, and 21, as explained below.

Group VII, claim(s) 1-3, 5, 6, 8-12, and 14-22, and 26, drawn to an inhibitory RNA molecule designed with reference to the sequence shown in Fig. 15, and to an expression cassette and vector thereof, and to a method for inhibiting division of a cancer cell comprising the use of said RNA molecule. Election of this group requires the further election of a single species of the claimed invention from claims 3, 15, 16, and 21, as explained below.

Group VIII, claim(s) 1-3, 5, 6, 8-12, and 14-22, and 26, drawn to an inhibitory RNA molecule designed with reference to the sequence shown in Fig. 16, and to an expression cassette and vector thereof, and to a method for inhibiting division of a cancer cell comprising the use of said RNA molecule. Election of this group requires the further election of a single species of the claimed invention from claims 3, 15, 16, and 21, as explained below.

The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special

technical features for the following reasons: The special technical feature of Groups I-VIII is, in turn, an inhibitory RNA molecule targeted to the nucleic acid sequence shown in Figure 9, 10, 11, 12, 13, 14, 15, or 16; and/or to a method of using said molecule to inhibit or treat cancer. As each sequence represents a different and unique gene (see page 21 of the specification), having a different nucleotide sequence, and encoding a different polypeptide, each gene defines a different and unique set of inhibitory RNA molecules and methods of use thereof for inhibiting said genes. Thus, Groups I-VIII lack unity of invention *a priori* because each group comprises a different special technical feature. Applicant is required to elect one Group for prosecution on the merits.

Further elections

Each of Groups I-VIII contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are distinguished by:

1. the type of cell into which the inhibitory RNA molecule is introduced (claim 3);
2. the type of promoter, cancer or cell specific, used to express an inhibitory RNA molecule (claims 15 and 16); and
3. the type of teratocarcinoma cancer treated by the method of claim 17.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each species represents a special technical feature---a different active step or treatment of a different patient population---not shared by any other species.

Applicant is required, in reply to this action, to elect a single species from each of categories 1-3 above to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 1, 8, and 17. Further, claim 20 is subgeneric.

Conclusion

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louis Wollenberger whose telephone number is (571)272-8144. The examiner can normally be reached on M-F, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached on (571)272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Louis Wollenberger/
Examiner, AU1635
March 28, 2008